TAB AA

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	M.D.L. No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris

REPORT OF INDEPENDENT EXPERT

PROFESSOR ERNST R. BERNDT

TO JUDGE PATTI B. SARIS

FEBRUARY 9, 2005

Professor Meredith Rosenthal discussed another concept and measure of "spread" that for a PBM referred instead to what the PBM charged the payor/insurer (e.g., AWP – f% + administrative fees) minus what the PBM reimbursed the pharmacy (e.g., AWP – g% + dispensing fee + administrative fee), in which case the PBM "spread" equaled g% - f% + differential fees.[23] Professor Rosenthal also appears to assert that for the self-administered drug classes, each class member must have a contractual relationship with a PBM.[24]

III. THE ORIGINS, EVOLUTION AND PERSISTENCE OF AWP AND "SPREAD"

A. Brand Name/Single Source Self-Administered Drugs

20. To understand today's interactions among drug manufacturers, wholesalers, retailers and PBMs, it is informative to consider briefly the history of how AWP, and differences between AWP and WAC, came into being, along with the important role of information and communications technology in affecting distribution costs and industry structure. Unfortunately, much of this history is anecdotal and oral, known by the legions of economists, industry consultants and attorneys involved in the now legendary Brand Name Drug Litigation involving branded (typically patent-protected) self-administered medications (orals, topicals, inhalants, self-injectables and other miscellaneous products). Interestingly, in the context of this litigation a hint of this history is given in the deposition of AstraZeneca's John R. Freeberry, on which I will comment further below.[25]

21. To the best of my knowledge, the first widely circulated written discussion of the AWP history is that by Professor E. M. (Mick) Kolassa, who in 1997 authored a textbook, *Elements of*

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[23] *Written Tutorial of Meredith Rosenthal*, Ph.D. presented before Judge Patti B. Saris, United States District Court for the District of Massachusetts, December 6, 2004, p. 16.
[24] *Written Tutorial of Meredith Rosenthal*, Ph.D., supra, p. 12.
[25] Deposition of John Richard Freeberry, May 20, 2004, pp. 168-172. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs' Reply to AstraZeneca Pharmaceuticals LP's Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

Pharmaceutical Pricing.[26] Substantial portions of the material in that text overlap, however, with paragraphs in an earlier 1994 peer-reviewed article,[27] as well as with presentational material prepared for previous marketing consulting/research seminars conducted by Professor Kolassa.[28] Kolassa [1997] begins by defining AWP as follows:

> "Neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times. Few, if any, wholesalers even consider AWP today when pricing their prescription products. It is, however, commonly used by retailers and others who dispense medications as the basis for many pricing decisions. Due to its availability from many sources, the AWP is often used as a surrogate for actual prices when studying prescription price trends".[29]

22. In Kolassa [1994a], the original *raison d'être* for AWP and for the now infamous common 20%-25% "spreads" between wholesalers' acquisition and retail pharmacy acquisition costs of branded self-administered drugs is recounted. Recall that during the 1980s, following the pioneering practices of WalMart and other "superbox" retailers, implementation of information and communications technological developments significantly impacted the rationalizing of wholesaler-retailer distribution logistics, the monitoring of transactions in real time, and the management of inventory, reducing costs and in the process leading to the demise of many small retail and wholesale firms. These phenomena also occurred in the context of pharmaceuticals.[30] Despite its length, the following quote from Kolassa [1994a] is illuminating:

> "The AWP, the most common figure used for drug price comparisons, is a vestige of a drug distribution system that disappeared in the early 1980s. Prior to that

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[26] E. M. (Mick) Kolassa, *Elements of Pharmaceutical Pricing*, Binghamton, NY: The Pharmaceutical Products Press, 1997.
[27] Mick Kolassa, "Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents", *Journal of Pain and Symptom Management*, 9(4), May 1994: pp. 235-243. Hereafter I denote this reference as Kolassa [1994a].
[28] See, for example, *Elements of Pharmaceutical Pricing: A two-day marketing research seminar*, Radisson Hotel & Suites, Fairfield, NJ, August 9-10, 1994. Hereafter I denote this reference as Kolassa [1994b].
[29] Kolassa [1997], *supra*, p. 30.
[30] For another discussion on the impacts of information and communications technology on wholesale-retail interactions in the pharmaceutical industry, see "Computers as Agents of Change" (pp. 61-65) and "Retailing Reorganized" (pp. 65-67) in John T. Fay, Jr., "The Wholesaler", ch. 12 in Mickey C. Smith, ed., *Principles of Pharmaceutical Marketing*, Third Edition, Philadelphia: Lea & Febiger, 1983.

time, there were several hundred small, independent drug wholesalers, each operating regionally. Due to the inefficiencies of such a fragmented system, the operating costs were quite high. The average markup above cost by these wholesalers to their retail customers, primarily pharmacies, was 20% to 25%, depending on manufacturer. The manufacturer differences were due to the fact that, while most pharmaceutical manufacturers used a wholesaler-only method of distribution to the retail class of trade, a significant number of large firms had invested in their own distribution networks and preferred 'direct' sales over the use of wholesalers. By convention, wholesalers added 20% to the price of products from companies following a wholesaler-only policy while adding 25% to the prices of products from those companies who chose to 'compete' with the wholesalers. At that time, virtually all pharmaceutical companies sold products directly to hospitals that did not use wholesalers. As a result, less than one-half of the pharmaceutical products sold in the United States were handled by drug wholesalers in the early 1970s. {Footnote in Kolassa [1994a] omitted.}

In the late 1970s and early 1980s, several wholesale drug companies began to acquire smaller competitors. At that time, a few companies expanded significantly, many becoming national in scope. As a result, there are fewer than 90 separate wholesaler drug companies today, with more consolidations expected in the next few years. The expansion of major firms also concentrated competition. Prior to this consolidation, most wholesalers had little or no competition, so there was little pressure to reduce their markups. The consolidation in the industry resulted in major wholesale companies competing for the same business. The net effect was price competition.

This expansion of major wholesalers led to greater efficiencies as the wholesalers adopted more sophisticated inventory control systems, and to the expansion of services offered to retail and hospital customers. Large wholesalers then used their competitive advantages to gain and keep new customers. The utilization of wholesalers increased substantially during this period, resulting in the wholesalers' handling of over 80% of prescription product sales by 1987. {Footnote in Kolassa [1994a] not reproduced here.}

Additionally, during the 1980s, the prices charged by the manufacturers began to increase. This allowed the wholesalers to practice arbitrage, buying drugs in anticipation of price increases, then selling their inventory at the new, higher prices. These combined forces brought the average wholesale markup today to roughly 2.5%, significantly lower than the markup implied by the published AWP.

Price-reporting services, however, still rely upon the AWP as their primary figure, because many companies publish only that figure (usually called the "suggested price to pharmacy"). A recent move by several manufacturers, however, is to publish only their own list prices, refusing to offer the traditional AWP figure. This has been done, reportedly, because many name-brand drug makers feel the

> AWP unfairly distorts their prices and results in competitive disadvantages. The AWP, although not the cost paid by retailers, still provides the basis for much retail pharmacy pricing, with retailers euphemistically referring to the difference between their actual cost and the AWP as 'earned discount'. This tradition is so ingrained that a retailer that sells a product at AWP, which is 12%-18% above their cost, refers to this price as a 'loss leader'."[31]

Kolassa summarizes this discussion by stating, "Within pharmacy circles, the definition of AWP, it is joked, is 'Ain't What's Paid.'"[32]

23. The evolution of the AWP – WAC "spread" for branded self-administered pharmaceuticals is therefore, as best I can tell, quite understandable, and apparently not the result of any sinister or nefarious conspiracies. Moreover, since AWP was publicly known, it served as a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically.

24. Why this "spread" practice has continued long after its underlying rationale has largely disappeared is a bit puzzling, but is I believe understandable and plausible. Given the AWP – WAC history, retail pharmacies plausibly continued to expect their acquisition costs to be 20-25% below AWP, and thus in their contracts with third party payors and PBMs, retailers generally expected to be reimbursed at 10-15% below AWP. In such a context, one can understand that a single manufacturer marketing a newly FDA approved drug would find it quite challenging if not impossible to successfully set an AWP that was only, say, 2-5% above the WAC, for with that small a differential, retailers would be unable to recover their acquisition costs, unless they renegotiated and rewrote contracts with PBMs and other third party payers (such contracts typically applied a uniform percent discount across all single source branded self-administered drugs, regardless of therapeutic class).[33]

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[31] Kolassa [1994], *supra,* pp. 236-237; much of this material is reproduced in Kolassa [1997], *supra*, pp. 33, 35-36.
[32] Kolassa [1994a], *supra,* p. 237.
[33] The percent figure typically varied, however, depending on whether the drug was a brand or generic.